

ERYTHROMYCIN - erythromycin gel
Glades Pharmaceuticals, LLC

Rx only

DESCRIPTION

Erythromycin Topical Gel USP contains 2% erythromycin, USP, (20 mg/g) in a vehicle consisting of 95% (w/w) alcohol (denatured with *tert*-butyl alcohol and denatonium benzoate), and hydroxypropyl cellulose. Erythromycin is a macrolide antibiotic obtained from cultures of *Streptomyces erythraeus* and is represented by the following structural formula. Its molecular weight is 733.94 and its molecular formula is C₃₇H₆₇NO₁₃.

CLINICAL PHARMACOLOGY

The exact mechanism by which erythromycin reduces lesions of acne vulgaris is not fully known; however, the effect appears to be due in part to the antibacterial activity of the drug.

Microbiology

Erythromycin appears to inhibit protein synthesis in susceptible organisms by reversibly binding to ribosomal subunits, thereby inhibiting translocation of aminoacyl transfer-RNA and inhibiting polypeptide synthesis. Antagonism has been demonstrated between erythromycin, lincomycin, chloramphenicol, and clindamycin.

INDICATIONS AND USAGE

Erythromycin Topical Gel is indicated for the topical treatment of acne vulgaris.

CONTRAINDICATIONS

Erythromycin Topical Gel is contraindicated in those individuals who have shown hypersensitivity to any of its components.

PRECAUTIONS

General

For topical use only; not for ophthalmic use. Concomitant topical acne therapy should be used with caution since a possible cumulative irritancy effect may occur, especially with the use of peeling, desquamating or abrasive agents.

Avoid contact with eyes and all mucous membranes. The use of antibiotic agents may be associated with the overgrowth of antibiotic-resistant organisms. If this occurs, discontinue use and take appropriate measures.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies to evaluate carcinogenic and mutagenic potential, or effects on fertility have not been performed with erythromycin.

Pregnancy

Teratogenic Effects

Pregnancy Category B

There was no evidence of teratogenicity or any other adverse effect on reproduction in female rats fed erythromycin base (up to 0.25% of diet) prior to and during mating, during gestation and through weaning of two successive litters. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used in pregnancy only if clearly needed.

Erythromycin has been reported to cross the placental barrier in humans, but fetal plasma levels are generally low.

Nursing Mothers

It is not known whether topically applied erythromycin is excreted in human milk. A decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

The most common adverse reaction reported with erythromycin topical gel was burning. The following have been reported occasionally: peeling, dryness, itching, erythema, and oiliness. Irritation of the eyes and tenderness of the skin have also been reported with the topical use of erythromycin. A generalized urticarial reaction, possibly related to the use of erythromycin, which required systemic steroid therapy has been reported.

DOSAGE AND ADMINISTRATION

Apply a thin film to affected area(s) twice a day, in the morning and the evening after the skin is thoroughly washed with soap and warm water and patted dry. The hands should be washed after application. If there has been no improvement after 6 to 8 weeks, or if the condition becomes worse, treatment should be discontinued, and the physician should be reconsulted.

HOW SUPPLIED

Erythromycin Topical Gel USP, 2% is supplied in sealed metal tubes in the following sizes:

30 g - NDC 59366-2462-3

60 g - NDC 59366-2462-5

NOTE: FLAMMABLE. KEEP AWAY FROM HEAT AND FLAME. Keep tube tightly closed. Store at controlled room temperature, 15°-30°C (59°-86°F).

Manufactured by

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for **Glades Pharmaceuticals, LLC**, Coral Gables, FL 33134

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